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In Re Bard IVC Filters Products
 Liability Litigation

No. MD-15-02641-PHX-DGC

DORIS JONES and ALFRED JONES, a
 married couple,

Plaintiffs,

v.

C.R. BARD, INC., a New Jersey
 corporation and BARD PERIPHERAL
 VASCULAR, an Arizona corporation,

Defendants.

**PLAINTIFF'S MOTION FOR
 RECONSIDERATION REGARDING
 ADMISSIBILITY OF CEPHALAD
 MIGRATION DEATH
 COMPLICATIONS ASSOCIATED
 WITH RECOVERY FILTER**

Assigned to the Honorable David G.
 Campbell)

(Oral Argument Requested)

Plaintiff submits this Motion for Reconsideration in accordance with L.R.Civ.
 7.2(g)(1) seeking reconsideration of the Court's Order [Doc. 10819, "Order"] ruling that
 evidence of deaths from cephalad migration of the Recovery filter is excluded under FRE
 403. As explained below, due to the truncated nature of how arguments were presented,
 the premise of the Order is now known to be wrong: the G2 design modification did not
 cure the problem of cephalad migration and—contrary to Bard's representations—
 cephalad migration continued to be associated with deaths in subsequent devices,
 including the Eclipse. Because evidence of Recovery filter cephalad migration deaths is
 relevant to this case and cannot practically be excised from the web of evidence relating to

1 the defective design of Bard's filters and its conduct in response to the Recovery deaths,
2 the Court should modify its Order to permit reasonable presentation of such evidence
3 consistent with CMO 31 [Doc. 10323].

4 **PROCEDURAL HISTORY**

5 In *Booker*, Bard's MIL #1 [Doc. 9862] sought to exclude *all* complications
6 associated with the Recovery filter and, as a result, Plaintiff's response briefing was broad
7 in scope, not limited to cephalad migrations. The Court denied Bard's motion [Doc.
8 10258], but reserved decision on the cephalad migration death evidence to be discussed
9 further at the final *Booker* pre-trial conference, which discussion resulted in Section j of
10 CMO 31 without further briefing. Plaintiff abided by CMO 31 and drew no objection
11 during the *Booker* trial related to the introduction of cephalad migration deaths.

12 For the *Jones* trial, the Court directed that the parties "re-urge" any *Booker* motions
13 *in limine* in a five-page brief. Mar. 29, 2018, Status Hearing Minute Entry, Doc. 10582.
14 In its brief, Bard re-urged three issues: Recovery filter development and complications,
15 Recovery cephalad migration deaths, and the FDA warning letter. Because Bard's re-
16 urged motion raised a new issue, namely the alleged distinctions between the G2 and
17 Eclipse filters, Plaintiff filed a five-page response to address that alleged distinction,
18 focusing on evidence demonstrating that, as this Court found in denying Bard's motion for
19 summary judgment, the Eclipse effectively is the G2 and why the evidence was relevant
20 to the Eclipse story. Because the issue of cephalad migration death evidence was teed up
21 in the context of re-urging of issues previously decided in *Booker* (and because what is
22 sauce for the G2 is sauce for the Eclipse and CMO 31 adequately balanced and curtailed
23 the use of cephalad migration deaths), only eleven lines in the brief were directed at the
24 specific issue of cephalad migrations.

25 During the April 13, 2018, hearing on the re-urged *Booker* motions *in limine*, the
26 Court inquired about cephalad migration frequency and deaths. Believing the
27 battleground issues to be those argued in Bard's brief (that the Eclipse was far removed
28 from the Recovery and that Mrs. Jones' mechanism of injury differed from cephalad

1 migration; in other words, the same arguments the Court rejected in *Booker*) Plaintiff
2 could not contest at that time Bard's claim that there were no cephalad migration deaths
3 after the Recovery and that the complication of cephalad migration was largely addressed
4 by G2 design changes. Tr. Proc. April 13, 2018, Ex. A, at 13:20-14:11. As set forth
5 below, Bard's representations were incorrect. And, in the absence of evidence of
6 cephalad migrations and death from later devices, those errors translated into bases for the
7 Order excluding cephalad migration death evidence. Order at 3 (noting that problem of
8 cephalad migration did not continue to any significant degree after the Recovery and that
9 cephalad migration deaths all occurred before the Recovery was taken off the market), 4
10 (noting that there were no deaths from cephalad migration with the Eclipse and that such
11 evidence was therefore not relevant to Mrs. Jones' punitive damages claim).

12 As set forth below, a thorough review of the Trackwise database and other evidence
13 shows that the problem of cephalad migration continued with the Eclipse filter and that
14 there were deaths and near-deaths from cephalad migration in Eclipse patients. Moreover,
15 evidence of deaths from cephalad migration cannot be neatly excised from other
16 complication evidence developed in this case. Affirming the Order would require
17 Plaintiff to try the case in a vacuum that would be confusing for the jury and misleading
18 as to central key issues, including omission of the reason Bard changed the design of the
19 G2 family of filters from the Recovery.

20 ARGUMENT

21 **I. The Order Is Premised Upon Inaccurate Information.**

22 As stated above, because the cephalad migration issue was presented as part and
23 parcel of Bard's G2 vs. Eclipse argument, Plaintiff was not in a position at the hearing to
24 rebut Bard's contention and the Court's perception that the G2 design changes largely
25 eliminated cephalad migration and that there were no cephalad migration deaths following
26 the Recover filter. While those factors form central bases of the Order, they are incorrect.

1 **A. Cephalad Migration Was Not Corrected in Later Devices.**

2 In balancing the relevancy of cephalad-migration-death evidence against the danger
3 of undue prejudice, the Court focused on the notion that the complication of cephalad
4 migration did not continue after the Recovery filter, based on Bard's representation that
5 "Bard fixed the issue it was having with the Recovery filter migrating to the heart" and the
6 Court's own notes from *Booker* reflecting only one instance of cephalad migration with
7 the G2. Order at 3; Ex. A. at 18:15-21.

8 However, a targeted review of the thousands of complaints in Bard's Trackwise
9 database compiled to address this issue reveals [REDACTED]
10 [REDACTED] See Representative Summary of Cephalad
11 Migrations and Case Reports from Trackwise re: Placement of G2 and Eclipse Filters, Ex.
12 B. Moreover, because there was no specific FDA code distinguishing caudal or cephalad
13 migrations until later in the evolution of the G2 filters, on multiple occasions migration
14 was reported with no characterization as to whether it was cephalad or caudal. This
15 problem, compounded [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 [REDACTED] makes it impossible to say that the problem of cephalad
19 migration did not continue to any significant degree.

20 Nor can it be said that ongoing cephalad migration did not play a role in the
21 contemplated re-design of the Eclipse filter only eight months after it was launched. See
22 Exhibit D, Memo from Bret Baird, September 30, 2010, BPVE-01-00545491. The product
23 opportunity appraisal for the next Eclipse design [REDACTED]
24 [REDACTED]
25 [REDACTED]
26 [REDACTED]
27 [REDACTED] See Exhibit E, Idea POA Eclipse Anchor
28

1 Filter, BPVE-01-02077858-BPVE-01-02077861.¹ Thus, it would be misleading for Bard
 2 to suggest that the complication of cephalad migration was largely “fixed” with the G2
 3 family redesign, and Plaintiff should not be denied a central part of the filter story at trial.

4 **B. There Were Deaths From Cephalad Migration With Other Devices,**
 5 **Including The Eclipse.**

6 The reports in Exhibit B demonstrate that cephalad migrations [REDACTED]

7 [REDACTED]
 8 [REDACTED]
 9 Ex. B complaint nos. [REDACTED] (discussing
 10 death from filter migration to heart in Eclipse patients). Exhibit B also demonstrates that
 11 there were a number of *near*-death events associated with cephalad migration in patients
 12 who were saved through emergent resuscitation or surgery following cephalad migration
 13 of filters or filter fragments. Ex. B complaint [REDACTED]

14 [REDACTED] complaint [REDACTED]

15 [REDACTED] complaint [REDACTED]

16 Bard’s own analysis of Eclipse cephalad migrations, including the deaths, confirms one of
 17 Plaintiff’s central theories—that Bard never conducted a thorough and effective root cause
 18 analysis and continued to sell retrievable IVC filters without understanding what was
 19 causing severe complications, including deaths. *See, e.g.,* Ex. B [REDACTED]

20 [REDACTED]
 21 [REDACTED]
 22 Thus, Bard’s contention that there were no cephalad migration deaths following

23 ¹ As set forth below, deaths from cephalad migration continued while the Eclipse was
 24 being sold, which is highly probative of Plaintiff’s claims that Bard failed to conduct a
 25 proper root cause analysis and did not act reasonably (but rather in conscious disregard of
 26 known deadly risks) in continuing to market the G2 line of filters (including Eclipse) in
 light of this evidence. [REDACTED]

27 [REDACTED] While such
 28 evidence may be harmful to Bard, it is not unfairly or unduly prejudicial because deaths
 occurred with the Eclipse filter.

1 the Recovery's removal from the market is simply not true and should not serve as a basis
2 for precluding Recovery cephalad migration deaths at trial.

3 **II. Cephalad Migration Is Relevant And Substantially Similar To Plaintiff's**
4 **Claims.**

5 The Court also found that deaths from cephalad migration should be excluded on the
6 basis that they are not substantially similar to the mechanism of failure for Mrs. Jones.
7 Order at 4-5. While Mrs. Jones did not experience cephalad migration, she does not seek
8 admissibility of cephalad migration death evidence as true Other Similar Incident or OSI
9 evidence. For the reasons found in *Booker*, this is simply not a product case involving
10 evidence of completely unrelated complications involving other products. Order re
11 Booker MILs, Doc. 10258, at 4-5. Rather such evidence is directly relevant to a number
12 of her claims. The Recovery cephalad migration deaths are directly relevant to the
13 defective design of the G2 (and thus the Eclipse). Specifically, the Recovery deaths are a
14 direct cause of the design change to the G2 (and thus the Eclipse) that increased size of its
15 base, which in turn (according to Dr. McMeeking) resulted in the G2 (and Eclipse) filter's
16 constellation of complications, caudal migration, tilt, fracture, and perforation (all of
17 which occurred with Doris Jones' filter). Thus, Recovery migration-related deaths were a
18 direct and proximate cause of the design defects in the G2 that resulted in the failures in
19 this case.² They are also relevant to the reasonableness of Bard's actions for Plaintiff's

20
21 _____
22 ² Bard's investigations into Recovery's cephalad migration arose only in the context and
23 as a result of migration deaths. There was no separate independent investigation into
24 cephalad migration apart from Bard's investigation into the deaths. In its root cause
25 analysis of these cephalad migrations Bard consistently concluded that it did not know
26 why the device was migrating to the heart. [REDACTED]

27 [REDACTED] That design
28 change caused a constellation of cascading failures in the G2 that were testified to by
numerous experts in the *Booker* case. According to Doctors Hurst and Muehrcke, the
Eclipse filter in Doris Jones migrated caudally, tilted, perforated, and fractured. Those are
all the result of the design defects in the G2 (and also the Eclipse).

1 negligent design claim and punitive damages, as this Court found in denying Bard's
2 summary judgment motion.

3 The Order analyzing how the Recovery deaths related to punitive damages was also
4 based, in part, on the notion that cephalad migration deaths stopped when the Recovery
5 was taken off the market in 2005. Order at 5. As explained above, that information is not
6 accurate. Thus, in the face of continued cephalad migrations, and some related to deaths,
7 and with Bard simultaneously reevaluating its design once again within months of the
8 Eclipse launch, evidence of Recovery filter deaths goes to Bard's state of mind for
9 punitive damages. Because the complication of cephalad migration continued with the G2
10 filter line (including Eclipse)³ and that some of those migrations were associated with
11 death and near-death injuries after entire filters were migrating to patients' hearts as seen
12 with the Recovery, there is substantial similarity regarding cephalad migration between
13 the Eclipse and Recovery filters and such evidence is admissible.⁴

14 **III. Recovery Filter Death Evidence Cannot Reasonably Be Extracted From The**
15 **Overall Complication Evidence.**

16 In its Order, this Court agreed that the fact of Recovery migrations is relevant as are
17 the actions Bard took in response to the migrations. But, there are not two separate and
18 distinct categories of evidence: Recovery-migration-death evidence is a subset of
19 Recovery-migration evidence. In fact, these two sets of evidence are essentially co-
20 extensive. The documents and testimony relating to Bard's investigation and response to
21

22 ³ [REDACTED]

23 [REDACTED]
24 [REDACTED]
25 [REDACTED]
26 [REDACTED]
27 ⁴ It would also be unfairly prejudicial to allow Bard to elicit unfounded testimony from
28 experts to the effect that filters are effective in preventing pulmonary emboli deaths while
precluding evidence of undisputed Recovery deaths.

1 Recovery cephalad migration exist only in the context of the deaths resulting from those
2 migrations, and Plaintiff cannot separate the cream from the coffee as to this evidence.

3 The process of investigating the Recovery cephalad migrations began with the first
4 death. At the time, Bard's product assessment team met and convened to set a plan to
5 investigate that death. *See* Tr.Ex. 1008, Ex. J; Dep. Tr. Len DeCant dated May 24, 2016,
6 Ex. K, at 252:1-254:2.

7 [REDACTED]
8 [REDACTED]
9 [REDACTED] Despite that alleged larger scope, Bard's
10 migration investigation focus was squarely on those that caused deaths and not smaller
11 non-fatal migrations. Bard's head of R&D at the time, Len DeCant, testified:

12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]
18 Ex. K at 268:14-270:9 (emphasis added).

19 Bard's investigation and analysis documents support this testimony. Over the course
20 of the next 10 months, [REDACTED]

21 [REDACTED]
22 [REDACTED]
23 [REDACTED] It is only in those
24 reports that Bard performed a root cause analysis – the lack of which is an essential part of
25 Plaintiff's claims for design defect. And, there are no documents reviewing or analyzing
26 Recovery migrations independent of the deaths; indeed, Plaintiff is aware of no Recovery
27 migration report that does not mention the deaths.
28

1 Because all of the evidence of Bard's investigation and decision-making concerning
2 Recovery migrations relate to or reference a death or deaths and rely on the facts relating
3 to the deaths (including frequency and severity) to come to conclusions, there is no
4 realistic way to remove the migration-death references from Bard's activities – they were
5 the basis for those actions. For example, there is no testimony regarding cephalad
6 migration investigation independent of the deaths. [REDACTED]

7 [REDACTED]
8 [REDACTED] It is simply not the case that the
9 parties can refer to testimony by Bard's witnesses addressing the migration issues and the
10 efforts to determine root cause without reference to the deaths.

11 As with the Court's ruling on the FDA evidence and testimony, Order Denying Pl.
12 MIL No. 1 [Doc. 9881] at 7, the evidence of the deaths is present throughout the relevant
13 Recovery migration evidence and cannot be readily extracted. Excising cephalad
14 migration death evidence from the larger Recovery (and thus G2 and Eclipse) story would
15 effectively neuter Plaintiff's ability to prove Bard failed to conduct a proper root cause
16 analysis, which is woven throughout her various claims.

17 The practical impact of the Order thus becomes immediately apparent. Within hours
18 of issuance of the Order, Bard sent at least twelve emails requesting that Plaintiff
19 withdraw substantial testimony and dozens of exhibits it claims are even remotely
20 connected with the cephalad migration death associated with the Recovery filter. But, as
21 noted above, that testimony and the related documents are the only evidence that exists
22 regarding the cephalad migrations of Recovery filters and Bard's investigation and actions
23 with respect to migration. Bard's proposed redactions would force Plaintiff to try her case
24 in a vacuum devoid of essential facts showing why the Eclipse was launched in the first
25 place. Exhibit O contains representative examples of redactions Bard claims are
26 mandated by the Order. As even a cursory examination will reveal, removing any
27 evidence touching on Recovery cephalad migration deaths would eliminate substantial
28

1 evidence of other complications in the cascade of failures.⁵ It is hoped that the Court did
2 not intend (or have reason to consider) such curtailment of Plaintiff's proof in this case.⁶
3

4
5 ⁵ Eliminating Recovery filter death evidence would hamstring Plaintiff's effort to prove
6 that the G2 and Eclipse lacked the necessary design changes to make a safe and non-
7 defective filter. Because Bard argued in *Booker* and is expected to argue in *Jones* that it is
8 a responsible company with ongoing product improvements to make its devices safer over
9 time, *Booker* Trial Tr., Day 11, Ex. P, at 2550:10-25, Plaintiff should be allowed to show
10 that the real purpose of the G2 and Eclipse release was to try to maintain Bard's market
11 share in the optional filter market, even as the lack of realistic and safer design changes in
12 its new models became increasingly evident to Bard. For example, [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]
17 [REDACTED]

18 This interpretation of the Order is
19 hopelessly overbroad. Inquiry into filter patient "deaths" is inextricably intertwined with
20 highly relevant testimony from Bard witnesses, experts and key opinion leaders. For
21 example, [REDACTED]
22 [REDACTED]

23 No explicit reference to
24 cephalad migration is made. Similarly, Bard seeks to eliminate all testimony from key
25 opinion leader Gary Cohen since his testimony related to deaths generally, without
26 explicit reference to cephalad migration. *Id.* at 1-3. Yet this would deprive Plaintiff of
27 powerful evidence that Bard knew about risks with its product but failed to tell physicians
28 about it, including the fact that the Recovery had been placed on a QC hold. *Id.* at 2. Len
DeCant was instrumental in Bard's IVC filter R&D department. Yet Bard seeks to strip
evidence of his testimony concerning lack of root cause analysis since that testimony
relates in some way to "deaths," even though cephalad migration is not mentioned. *Id.* at
3-12. [REDACTED]
[REDACTED]

29 In Bard's view, anything touching
on death is completely off limits now. Bard's sweeping interpretation of the Order would
make a mess of the presentation of evidence at trial.

1 **IV. The *Booker* Limiting Admonition From CMO 31 Is Adequate To Prevent**
2 **Overuse At Trial Of Cephalad Migration Death Evidence in *Jones*.**

3 In light of the high level of relevance cephalad-migration-death evidence has to a
4 wide array of issues in *Jones*, its probative value is not outweighed by the danger of undue
5 prejudice. Should the Court reconsider its Order and allow evidence of cephalad
6 migration deaths, Plaintiff will avoid “overplaying” her hand with this evidence and
7 ensure, consistent with the mandate of CMO 31, that presentation of such evidence is
8 focused and targeted to those issues identified above.

9 **CONCLUSION**

10 For these reasons, Plaintiff requests that the Court reconsider its Order and allow
11 limited evidence of cephalad migration deaths consistent with CMO 31.

12 RESPECTFULLY SUBMITTED this 23rd day of April 2018.

13 GALLAGHER & KENNEDY, P.A.

14
15 By: /s/ Mark S. O'Connor

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CERTIFICATE OF SERVICE

I hereby certify that on this 23rd day of April 2018, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Gay Mennuti